IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
NEW ALBANY DIVISION

COMEDICA INCORPORATED,	)	
	)	**Case No. 4:23-cv-000026**
Plaintiff,	)	
	)	
vs.	)	
	)	
HILL-ROM SERVICES, INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

COMPLAINT

Plaintiff Comedica Incorporated ("Plaintiff" or "Comedica") brings this action against Defendant Hill-Rom Services, Inc. ("Defendant" or "Hill-Rom") for damages to remedy Defendant's breach of contract related to Comedica's MetaNeb® device. In support of this Complaint, Plaintiff alleges and states as follows:

Introduction

1. This Complaint arises from the Defendant's breach of contract in which Plaintiff licenses the right to Defendant to exclusively manufacture and market the MetaNeb® device in exchange for Acute Care and Post-Acute Care royalty payments derived from revenue generated from sales of the unit. MetaNeb® is a medical device that delivers a combination therapy to the lungs in order to expand the airways, deliver medication and remove secretions.

2. In 2009, Hill-Rom approached Plaintiff regarding the acquisition of all of Plaintiff's rights, title and interests in and to MetaNeb® with the intent to develop it for hospital use ("Acute Care"), and thereafter, to develop and release a home care ("Post-Acute Care") version of the device. Comedica and Hill-Rom entered a Business Development Agreement on November 6, 2009 (the "Acute Care Agreement," attached hereto as Exhibit A) as a result of these negotiations.

On February 1, 2014, Comedica and Hill-Rom entered a Post-Acute Care Exclusive License Agreement (the "Post-Acute Care Agreement," attached hereto as Exhibit B) to further define their agreements related to the planned refinement and enhancement of MetaNeb® into a home care device.

3. In February 2021, Defendant introduced an enhanced and/or a refined home care version of MetaNeb® named "Volara." Defendant failed (and subsequently refused) to pay royalties to Comedica for revenue generated from Volara as required by the "Post-Acute Care Agreement."

4. Comedica brings this action to obtain damages for losses and future royalties related to Defendant's breach of contract and patent infringement.

Parties

5. Comedica Incorporated ("Comedica or "Plaintiff"), is a for-profit corporation incorporated in the State of Texas with a principal place of business in Dallas, Texas.

6. Hill-Rom Services, Inc. ("Hill-Rom" or "Defendant") is a for-profit corporation doing business in Indiana. Hill-Rom is incorporated in the State of Indiana with a principal place of business in Cook County, Illinois.

Jurisdiction and Venue

7. This Court has original jurisdiction of the Plaintiff's civil action pursuant to 28 U.S.C. § 1332(a) because the amount in controversy exceeds the value of $75,000 and the dispute is between citizens of different states.

8. Venue is proper in this Court under 28 U.S.C. §1391 because: (i) Hill-Rom resides in this District and conducts a substantial amount of business in this District; and (ii) a substantial

part of the events or omissions giving rise to the claim occurred, and continue to occur, in this District.

9. Venue is also proper in this Court pursuant to the forum selection clause in the Acute Care Agreement and Post-Acute Care Agreement to file suit in either Ripley County, Indiana, or the United States District Court in the Southern District of Indiana.

General Allegations

10. In December 2005, Dee Faram ("Faram") and J. Kevin Cook ("Cook"), owners and principals of Comedica, conceived and developed the MetaNeb® System.

11. The MetaNeb® System was designed to mobilize retained secretions, provide lung expansion therapy, and to deliver medicated aerosol for the treatment and prevention of pulmonary atelectasis. It also has the ability to provide supplemental oxygen when used with compressed oxygen.

12. The MetaNeb® System offers three treatments which can be combined for maximum efficiency for patients and clinicians:

a. CHFO (Continuous High Frequency Oscillation) – a pneumatic form of chest physiotherapy that delivers medicated aerosol while oscillating the airways with continuous pulses of positive pressure.

b. CPEP (Continuous Positive Expiratory Pressure) – supplies medicated aerosol combined with continuous positive pressure to help hold open and expand the airways.

c. Aerosol – for the delivery of aerosol only. In this mode CHFO and CPEP are unavailable.

13. The MetaNeb® System supplies a platform from which CHFO and CPEP can be administered continually. This composite therapy is referred to as "MetaTherapy" Treatment. MetaTherapy® is a combination therapy that seamlessly alternates between CPEP and CHFO modes.

14. MetaTherapy® is a convenient treatment option for patients because of the following features:

a. Simple "connect and go" design;

b. Single patient use (SPU) circuit which includes a mouthpiece, nebulizer, mask/trach adapter, and in-line ventilator setup;

c. Allows the user to quickly switch between therapy cycles; and

d. Has an easily adjustable flow, pressure, and percussive rate.

15. Delivery options for MetaTherapy® include in-line ventilation, mouthpiece, face mask, and tracheostomy.

16. MetaTherapy® treats the following conditions: Chronic Obstructive Pulmonary Disease (COPD), post-operative airway management, Bronchiectasis, neuromuscular disorders, Cystic Fibrosis, Asthma, Emphysema, reversal of atelectasis, and chest wall trauma.

17. The effectiveness of MetaNeb has been established through various published studies and white papers, including but not limited to the "Hill-Rom White Paper," the "American College of Surgeons Journal Publication," attached hereto as Exhibits C and D, respectively.

18. A recent study showed the MetaNeb® therapy to reduce post-operative pulmonary complications by over 30%. Additionally, MetaNeb® therapy reduced hospital length-of-stay by 1.6 days, ICU length of stay-of-stay by 2 days, and time on a ventilator by 64%.

19. MetaNeb® is currently in approximately 4,800 hospitals in the United States with

revenues estimated at $20 million per year.

20. In 2009, Hill-Rom approached Plaintiff with a desire to acquire all of Plaintiff's rights, title, and interests in and to MetaNeb®.

21. Plaintiffs shared with Hill-Rom their manufacturing, design, intellectual property, customer lists and revenue of the MetaNeb® device then being manufactured and sold for hospital use ("Acute Care"), and thereafter, their intent to develop and release a version of the device for use at home ("Post-Acute Care").

22. Prior to the negotiations and up until the Volera™ System was introduced, the only treatment option for in-home use was The Vest® Airway Clearance System, which is an inflatable garment attached by air hoses to an air pulse generator that rapidly inflates and deflates the inflatable garment to help dislodge mucus from the bronchial walls and mobilize secretions and mucus from the smaller to larger airways where it can be cleared by coughing or suctioning.

23. On November 6, 2009, Comedica and Hill-Rom entered a Business Development Agreement (the "Acute Care Agreement," attached hereto as Exhibit A) granting the Defendant the exclusive right to make and sell the MetaNeb® device.

24. Plaintiff continued to work with Hill-Rom to assist in improving the acute-care device and develop an at-home device, including researching compressors that would suffice for an at-home unit and other needed refinements and enhancements to the existing MetaNeb® device.

25. On February 1, 2014, Comedica and Hill-Rom entered the Post-Acute Care Exclusive License Agreement (the "Post-Acute Care Agreement," attached hereto as Exhibit B) granting Defendant an exclusive right to "make, have made for it, use, sell or lease, offer to sell or lease, and/or import Products" in the "Post-Acute Care Field."

26. Under the Post-Acute Care Agreement (collectively, referred to herein as the "Agreements"), Comedica granted Hill-Rom rights to make and sell devices incorporating the MetaNeb® system, ***including refinements and enhancements*** to that system and those devices, for Post-Acute Care, in exchange for specified royalty payments.

27. According to the Agreements, "Product" and "Products" are defined as:

> " . . . the Existing Product, the Post Acute Product, and any other Systems covered by Comedica Intellectual Property that are in full force and effect, including any disposables or components or subassemblies relating thereto; provided, however, that no Systems, including any Existing Product, Post Acute Product, or any disposable or component or subassembly relating thereto, shall be deemed to be a Product unless it is covered by one or more valid claims of Comedica Intellectual Property that are in full force and effect."

28. The "Existing Product" is the MetaNeb® device according to the Agreements.

29. The "Post-Acute Product" is "**the Existing Product *plus additional refinements and enhancements*** identified by Hill-Rom, if any, for use of the Post-Acute Product in the Post-Acute Field" according to the Agreements. [Emphasis added].

30. "System" or "Systems" means "therapeutic systems indicated for mobilization of secretions, lung expansion theory, and the treatment and prevention of pulmonary atelectasis, including all hardware, software, disposables, accessories, and components therefore and/or relating thereto" according to the Agreements.

31. The "Post-Acute Care Field" means "all healthcare service providers not included in the Acute Care Field, including, but not limited to patients' homes, physicians' offices, assisted living and long-term care facilities" according to the Agreements.

32. As consideration for receiving the exclusive right to make and sell MetaNeb® devices, including enhancements and refinements thereto, in the Post-Acute Care Field, Defendant agreed to pay royalties to Plaintiff.

33. Between February 2014 and February 2021, Hill-Rom, with the help of Comedica, Faram and/or Cook, worked to develop an at-home version of MetaNeb® for Post-Acute Care. *See* https://www.youtube.com/watch?v=EHihhCmZ-RE.

34. In February 2021, Defendant introduced an enhanced and/or a refined version of MetaNeb® to market and sell in both the Acute Care Field and Post-Acute Care Field. Defendant re-named this device, Volara™.

35. The characteristics of MetaNeb® and Volara™ devices are identical in each of the following instances:

- FDA Intended Use Statement
- Small-Volume Nebulizer in Circuit
- Venturi in Circuit
- Entrainment Ports in Circuit
- Oscillatory Mode (CHFO)
- Constant Flow Mode (CPEP)
- Aerosol Delivered During Each Mode
- Aerosol Only Mode
- Adjustable Flow
- Oscillation Frequency Options
- Adjustable Pressure
- Pressure Monitoring
- 2½ Minute Alternating Modes of Combination Therapy (MetaTherapy = OLE Therapy)
- Patient Connections of Mouthpiece, Mask, or Endotracheal Tube

- Accommodates In-Line Use of Ventilator

36. The MetaNeb® and Volara™ devices both implement the operational therapy mode terms on the face of the devices, "CHFO" and "CPEP," which are unique acronyms only previously associated with MetaNeb®.

37. The MetaNeb® and Volara™ both use an aerosol function for use in delivering medicated aerosol for the treatment and prevention of pulmonary atelectasis.

38. Additionally, Defendant markets the Volara™ devices using the same studies and marketing materials, including efficacy calculations, as previously used for the MetaNeb® devices.

39. Defendant has publicly recognized that Volara™ is the at-home version of MetaNeb® "delivering the exact same therapy" and "proven outcomes" as the acute care system. *See* https://www.youtube.com/watch?v=EHihhCmZ-RE.

40. The U.S. Food and Drug Administrative also determined that the MetaNeb® and the MetaNeb® IV System are "substantially equivalent" to the Volara™ system in a letter to Defendant dated February 14, 2020, which is attached hereto as Exhibit E.

41. After unveiling its enhanced oscillation and lung expansion therapy system for Post Acute Care, Hill-Rom began referencing Volara™ in place of MetaNeb® and MetaTherapy® in previously used marketing materials. For example, YouTube videos with 3D animations for the products are nearly identical but for the removal of MetaNeb® and MetaTherapy® and the addition of Volara™. *See https://www.youtube.com/watch?v=mLuWHI0aaoE* (the MetaNeb® video) and *https://www.youtube.com/watch?v=WM_zXX5nnOA* (the Volara™ video).

42. The Volara™ device constitutes an enhancement and/or refinement of the MetaNeb® system requiring Defendant to pay royalties to Comedica from its Post-Acute Care Net

Sales. The Volara™ device, including its electromechanical component and user-friendly interface, is exactly what was contemplated by Hill-Rom and Comedica by including "enhancements and refinements" into the definition of Post-Acute Care Products because the parties recognized that MetaNeb®, as it existed when the Post-Acute Care Agreement was entered, would need these improvements before being released and marketed for Post-Acute Care.

43. After the introduction of Defendant's Volara™ device, Comedica became concerned that Defendant intended to breach its contractual obligations by refusing to pay royalties on the revenue generated from the Volara™ device.

44. On September 20, 2021, Comedica requested an audit of Post-Acute Care Net Sales to identify the revenue generated by MetaNeb®/ Volara™. In response, Defendant held a Zoom meeting with Comedica during which it informed Comedica that it did not intend to pay any royalties on revenue generated through the sales of Volara™ in the Post-Acute Care Field.

45. Nonetheless, Comedica completed its audit, which revealed that Defendant generated significant revenue from the sale of Volara™ in the Post-Acute Care Field from October 1, 2018 through September 30, 2021.

46. The audit reveals that Defendant should have paid royalties to Comedica from Volara™ sales through September 30, 2021 in the amount of $499,047.00.

47. Since September 30, 2021, Defendant has continued selling and marketing Volara™ devices while refusing to pay royalties to Comedica as required under the Acute Care Agreement or Post-Acute Care Agreement.

Count I – Breach of Contract

48. Comedica incorporates the allegations in the preceding paragraphs as if fully set forth herein.

49. Defendant executed and entered the Acute Care Agreement and Post-Acute Care Agreement with Comedica, which required Defendant to pay royalties on sales of the MetaNeb® system, including all enhancements and refinements.

50. The Acute Care Agreement and Post-Acute Care Agreement are binding contracts and Defendant's performance under the contracts was not excused.

51. Defendant has failed and refused to pay royalties to Comedica on sales of Volara™ devices, which constitute enhanced and/or refined versions of the MetaNeb® system.

52. Defendant materially breached its contractual obligations with Comedica by failing to pay royalties to Comedica on Volara™ sales.

53. Comedica's breach has harmed Defendant by no less than $499,047.00, which continues to accrue.

Count II – Declaratory Judgment

54. Comedica incorporates the allegations in the preceding paragraphs as if fully set forth herein.

55. There is an actual and present controversy between the parties.

56. Comedica contends that the Agreements require Defendant to pay royalties for sales of the Volara™ devices in the Post-Acute Care Field because they constitute enhancements or refinements of MetaNeb® rendering them Post-Acute Products under the Agreements.

57. Defendant denies these contentions.

58. Comedica seeks a judicial declaration that the Agreements require Defendant to make royalty payments to Comedica for all future sales of the Volara™ devices in the Post-Acute Care Field.

Prayer for Relief

WHEREFORE, Plaintiff Comedica Incorporated, by counsel, respectfully requests that this Court grant it the following:

1. A declaratory judgment that Defendant is required to make royalty payments to Comedica for all future sales of the Volara™ devices in the Post-Acute Care Field;

2. Damages resulting from Defendant's breach of contract for failing and/or refusing to pay royalties from prior sales of the Volara™ devices; and

3. Any other such further relief to which Comedica may be entitled as a matter of law or equity, or which the Court determines to be just and proper.

Jury Demand

Plaintiff respectfully requests a trial by jury, pursuant to Fed. R. Civ. P. 38(b), on all issues so triable.

Respectfully submitted,

COHEN AND MALAD, LLP

/s/ Michael W. McBride

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